The clinical evaluation of the effectiveness of two oral probiotic strains on gingival health.

Published: 04-04-2018
Last updated: 11-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46824

Source
ToetsingOnline

Brief title
The PrOH-ACT study

Condition

- Other condition

Synonym
gum disease

Health condition

mondgezondheid

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Source(s) of monetary or material Support: door ACTA Dental Research;met Symrise AG als subsidiebron,Symrise AG, Duitsland

Intervention

Keyword: double-blind randomised study, gingivitis experiment, oral health, probiotics

Outcome measures

Primary outcome

The main study parameter is the status of the gingival health of the participants: bleeding of the gingiva on marginal probing (BOMP). This will be documented to follow the gingival health status before, during and after the intervention and challenge.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks and burden related to this study are judged to be very limited. The time burden per research visit is at most 30 to 40 minutes. The induction of mild (short term, temporarily/reversible) gingival inflammation is a well-established method. The mild inflammatory status is completely reversible without long term risk or effects on dental health.

Secondary outcome

The secondary goal of this study is to follow the dynamics of immunological (a panel of interleukins and cytokines) and microbiological (microbial composition and diversity) aspects of the oral cavity.

Study description

Background summary

In the current study we will evaluate the effectiveness of two well defined probiotic strains, Lactobacillus paracasei LPc-G110 (CCTCC M 2013691) and Lactobacillus plantarum GOS42 (DSM 32131), in strengthening the oral ecosystem. These strains were selected from a panel of probiotic strains as the first mentioned was most potent in reducing the proportions of several anaerobic genera in ex vivo oral biofilms and the second was very effective in modulating the immune response in a model for gingival immune reactions. After supplementing the oral ecosystem with these probiotics or a placebo for 14 days, we will examine the (strengthened) resilience of the oral ecosystem using a two-week experimental gingivitis model by following the dynamics of clinical, immunological and microbial parameters. After experimental gingivitis, the volunteers will resume their normal oral hygiene routine and stop using the food ingredient. Two weeks later, when the effects of the experimental gingivitis have been reversed, we will examine the oral ecosystem once more to assess to what extent the modulating effects of L. paracasei and L. plantarum on the oral microbiome/ecosystem are still present.

Study objective

The primary objective is to evaluate clinically the effectiveness of two oral probiotic strains, compared with a placebo-group, on the gingival health during a two-week wash-in phase followed by a two-week period refraining from oral hygiene and a two-week wash-out phase. The secondary objective is to explore the dynamics of immunological and microbiological aspects of the oral cavity for the duration of the wash-in phase, the experimental gingivitis phase and the wash-out phase concerning the use of the two oral probiotic strains compared with the placebo-group.

Study design

This study is a single-centre, intervention, double-blind, parallel group (3) randomised, placebo-controlled clinical trial.

Intervention

Subjects are instructed to use one lozenge, 3 times daily after each meal, with the probiotic Lactobacillus plantarum (group A), with the probiotic Lactobacillus paracasei (group B) or lozenges without probiotics (placebo group). The challenge intervention is based on a full mouth experimental gingivitis protocol. For this, subjects will be requested to refrain from any form of oral hygiene for two weeks, resulting in plaque accumulation, temporarily leading to induction of mild gingival inflammation.

Study burden and risks

The risks and burden related to this study are judged to be very limited. The time burden per research visit is at most 30 minutes. The induction of mild (short term, temporarily/reversible) gingival inflammation is a well-established method. The mild inflammatory status is completely reversible without long term risk or effects on dental health.
Determination of the clinical parameters are part of standard dental clinical care. In addition, the collection of samples (saliva, plaque) during the study do not require invasive procedures. The probiotic strains, L. paracasei and L. plantarum, are present in various fermented food products and comply with the Qualified Presumption of Safety (QPS) status given by European Food Safety Authority (EFSA). Besides they are both available in many over-the-counter probiotic food ingredients targeted at gut health and oral health.
There is no direct benefit for the participants. The aim of the food ingredients are to sustain oral health in healthy individuals, therefore the effects of these ingredients are examined in an orally and systemically healthy population. As the outcomes of this study could support oral health and prevent oral disease, the very limited burden for the subjects is considered acceptable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Willing and able to give written informed consent and willing and able to comply to all study procedures; Adult, * 18 years - 55 years; Systemically healthy, as assessed by a medical questionnaire (no systemic diseases); Minimum of 20 natural teeth: at least the first or second molar must be present in each quadrant; Having visited the dentist for a regular check-up within the last year and having finished the necessary treatment(s);

Exclusion criteria

ACTA dental student or ACTA employee; Participation in a clinical study within the previous 30 days; Allergy/Intolerance to the test and placebo products (ingredients) in particular lactose and milk protein content (allergens) in the test products; not having a good general health and/or oral health.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2018

Enrollment:	117
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65326.048.18